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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/727,358	12/03/2003	Richard N. Kolesnick	1216-1-006CIP	5499
23565 7590 01/11/2007 KLAUBER & JACKSON 411 HACKENSACK AVENUE HACKENSACK, NJ 07601			EXAMINER WHITEMAN, BRIAN A	
			ART UNIT	PAPER NUMBER
			1635	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		01/11/2007	PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/727,358	<b>Applicant(s)</b> KOLESNICK ET AL.	
	<b>Examiner</b> Brian Whiteman	<b>Art Unit</b> 1635	

**– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 16 October 2006.  
 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.  
 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 7,9-15,17-20,34-44 is/are pending in the application.  
     4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
 6) ☒ Claim(s) 7,9-15,17-20,34-44 is/are rejected.  
 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.  
 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \*    c) ☐ None of:  
         1. ☐ Certified copies of the priority documents have been received.  
         2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
         3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/16/06</u> .  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Claims 7, 9-15, 17-20, and 34-44 are pending.

Applicant's traversal, the amendment to claims 7, 9-12, and 17-20, the addition of claims 34-44 and the cancellation of claims 1-6, 8, 16, 21-33 filed on 10/16/06 is acknowledged and considered by the examiner

#### ***Information Disclosure Statement***

The information disclosure statement (IDS) submitted on 10/16/06 was filed after the mailing date of the non-final rejection on 5/16/06. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

The information disclosure statement filed 10/16/06 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered. Only the abstract of several of the non-patent literature publications (CB-CD) is provided and CE is missing. The IDS lists the entire pages of these document, but only provides the abstracts.

#### ***Priority***

In view of applicant's argument, SEQ ID NO: 5 in the instant application enjoys priority to 5/30/02.

### ***Claim Objections***

Claims 42 and 44 are objected to because of the following informalities:

A series of singular dependent claims is permissible in which a dependent claim refers to a preceding claim which, in turn, refers to another preceding claim.

A claim which depends from a dependent claim should not be separated by any claim which does not also depend from said dependent claim. It should be kept in mind that a dependent claim may refer to any preceding independent claim. In general, applicant's sequence will not be changed. See MPEP § 608.01(n)

If the claims are allowed they will have to renumbered.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 7, 9-15, 17-20, and 34-44 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

New Matter rejection:

The limitation 'SEQ ID NO: 5, wherein the oligonucleotide is from about 8 to 50 nucleotides in length' in amended claim 7 and claims dependent therefrom, the limitation 'from about 8 to 50 nucleotides in length which is complementary to SEQ ID NO: 5' in claim 12 and claims dependent therefrom, the limitation 'SEQ ID NO: 5, wherein said nucleic acid inhibits the expression of KSR and is from about 8 to 50 nucleotides in length' in claims 15 and 20 and claims dependent therefrom is not supported by the instant specification. There appears to be no written description of the limitation in the application as filed. See MPEP § 2163.06. Applicant cites paragraphs 68 and 129 and for the limitation. Paragraph 68 recites:

The term "oligonucleotide," as used herein in referring to a nucleic acid of the present invention, is defined as a molecule comprised of two or more ribonucleotides, preferably more than three. Its exact size will depend upon many factors which, in turn, depend upon the ultimate function and use of the oligonucleotide. In particular, and in accordance with the present invention, the oligonucleotide should particularly associate with the RNA encoding KSR and should be of the appropriate sequence and size or length so as to specifically and stably associate with the target RNA such that expression (i.e., translation) of the RNA is blocked or such that stability of the RNA is negatively affected. In one particular aspect of the invention, the antisense oligonucleotides of the present invention are from about 8 to about 50 nucleotides in length, particularly oligonucleotides from 10 to 30 nucleotides in length, particularly oligonucleotides from 15 to 25 nucleotides.

Paragraph 129 recites:

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The oligonucleotides in accordance with this invention preferably are from about 8 to about 50 nucleotides in length. Particularly preferred oligonucleotides are from 10 to 30 nucleotides in length, particularly preferred are from 15 to 25 nucleotides. In the context of this invention it is understood that this encompasses non-naturally occurring oligomers as hereinbefore described, having 8 to 50 monomers.

The limitations in the amended and new claims are not disclosed in the paragraphs cited by the applicant. These paragraph do not disclose a nucleic acid that is complementary to SEQ ID NO: 5, wherein the nucleic acid is 8 to 50 nucleotides long. SEQ ID NO: 5 is 18 nucleotide longs and the specification does not describe what oligonucleotides having 8 to about 50 nucleotides in length can be complementary to SEQ ID NO: 5. If the oligonucleotide is longer than 18 nucleotides the specification does not disclose what nucleotides can be included to make a nucleotide that is 50 nucleotides long. If the nucleotide is shorter than 18, the specification does not disclose what nucleotides can be excluded. Therefore, there is nothing in the specification that supports the new limitation as set forth in the instant claims.

“It is not sufficient for purposes of the written description requirement of Section 112 that the disclosure, when combined with the knowledge in the art, would lead one to speculate as to modifications that the inventor might have envisioned, but failed to disclose.” *Lockwood v. American Airlines Inc.*, 41 USPQ2d 1961, 1966 (CAFC 1997).

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The claimed product reads on a sequence that is 8 to 50 base pairs long and is substantially complementary to SEQ ID NO: 5 (18 base pairs).

The term ‘substantially complementary’ indicates that the sequence does not have to 100% complementary to SEQ ID NO: 5 (see paragraph 0139).

The term “complementary” in claim 36 is broad and reads on any sequence that has a region complementary to SEQ ID NO: 5.

The term “pharmaceutical” and “therapeutically effective amount” in claims 17, 18, 39, and 40 does not have patentable weight over the prior art. See MPEP 2111-2111.02.

Claims 7, 17, 18, and 34-36 are rejected under 35 U.S.C. 102(b) as being anticipated by Griffais (WO 99/27105, sequence search result #9). Griffais teaches an oligonucleotide (SEQ ID NO: 20) that is 20 nucleobases and is substantially complementary to SEQ ID NO: 5. The oligonucleotide would have to be in a solution when in use thus reading on a composition comprising an excipient. The first page of the WO document and the sequence search result instead of the entire WO document is provided on the PTO-892 because the WO document is 1900+ pages. Upon request by applicant the entire WO document will be provided.

**A REFERENCE TEACHING PRODUCT APPEARING TO BE SUBSTANTIALLY IDENTICAL IS MADE THE BASIS OF A REJECTION, AND THE EXAMINER PRESENTS EVIDENCE OR REASONING**

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**TENDING TO SHOW INHERENCY, THE BURDEN SHIFTS TO THE APPLICANT TO SHOW AN UNOBVIOUS DIFFERENCE**

“[T]he PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his [or her] claimed product. Whether the rejection is based on inherency’ under 35 U.S.C. 102, on prima facie obviousness’ under 35 U.S.C. 103, jointly or alternatively, the burden of proof is the same...[footnote omitted].” The burden of proof is similar to that required with respect to product-by-process claims. *In re Fitzgerald*, 619 F.2d 67, 70, 205 USPQ 594, 596 (CCPA 1980) (quoting *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433-34 (CCPA 1977)).

**MPEP 2112.01:**

**PRODUCT AND APPARATUS CLAIMS X WHEN THE STRUCTURE RECITED IN THE REFERENCE IS SUBSTANTIALLY IDENTICAL TO THAT OF THE CLAIMS, CLAIMED PROPERTIES OR FUNCTIONS ARE PRESUMED TO BE INHERENT**

Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the prima facie case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. *In re Best*, 562 F.2d at 1255, 195 USPQ at 433.

Claims 7, 9-11, 17, 18, 19, 34-36, 38-41 and 43-44 are rejected under 35 U.S.C. 102(e) as being anticipated by Bennett et al. (US 6,329,203). Bennett et al. teach an antisense oligonucleotide that is at least 8 nucleobases (SEQ ID NO: 81) and up to 50 nucleobases and is substantially complementary to SEQ ID NO: 5 (columns 81-84). Bennett et al. teach the limitation in claims 9 and 10 (column 13). Bennett et al. teach the limitation in claims 11, 13, 17, 18, 34, 35, 36, 37, 38, 39, 40, 42, 43, 44 (columns 6 and 81-84). Bennett et al. teach the limitation in claims 19 and 41 (columns 25-26).

**A REFERENCE TEACHING A PRODUCT APPEARING TO BE SUBSTANTIALLY IDENTICAL IS MADE THE BASIS OF A REJECTION, AND THE EXAMINER PRESENTS EVIDENCE OR REASONING TENDING TO SHOW INHERENCY, THE BURDEN SHIFTS TO THE APPLICANT TO SHOW AN UNOBVIOUS DIFFERENCE**

“[T]he PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his [or her] claimed product. Whether the rejection is based on inherency’ under 35 U.S.C. 102, on prima facie obviousness’ under 35 U.S.C. 103, jointly or alternatively, the burden of proof is the same...[footnote omitted].” The burden of proof is similar to that required with respect to



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product-by-process claims. *In re Fitzgerald*, 619 F.2d 67, 70, 205 USPQ 594, 596 (CCPA 1980) (quoting *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433-34 (CCPA 1977)).

MPEP 2112.01:

**PRODUCT AND APPARATUS CLAIMS X WHEN THE STRUCTURE RECITED IN THE REFERENCE IS SUBSTANTIALLY IDENTICAL TO THAT OF THE CLAIMS, CLAIMED PROPERTIES OR FUNCTIONS ARE PRESUMED TO BE INHERENT**

Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the prima facie case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. *In re Best*, 562 F.2d at 1255, 195 USPQ at 433.

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all

obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35

U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

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evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 12-15 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bennett et al. (US 6,329,203) taken with Srivastava (US 6,261,384). Bennett et al. teach an antisense oligonucleotide that is at least 8 nucleobases (SEQ ID NO: 81) and up to 50 nucleobases and is substantially complementary to SEQ ID NO: 5 (columns 81-84). However, Bennett does not specifically teach a vector comprising the DNA comprising the antisense oligonucleotide, wherein the DNA is operably linked to a promoter.

However, at the time the invention was made, Srivastava teaches a vector comprising an antisense sequence (columns 21-22). Srivastava teaches using the vector to sufficiently integrate the sequence into a cell (columns 1-3).

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to combine the teaching of Bennett taken with Srivastava, namely to produce a vector comprising the DNA comprising the antisense oligonucleotide. One of ordinary skill in the art would have been motivated to combine the teaching to sufficiently integrate the DNA into a cell.

Therefore the invention as a whole would have been *prima facie* obvious to one ordinary skill in the art at the time the invention was made.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Whiteman whose telephone number is (571) 272-0764. The examiner can normally be reached on Monday through Friday from 7:00 to 4:00 (Eastern Standard Time), with alternating Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Douglas Schultz, PhD, SPE – Art Unit 1635, can be reached at (571) 272-0763.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of

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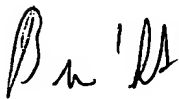
such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Fax Center number is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Brian Whiteman

A handwritten signature in black ink, appearing to read 'Brian Whiteman'.